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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,793	10/24/2001	Robert Johan Joseph Hageman	BO 42384	8792

466 7590 07/14/2004

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EXAMINER	
KHARE, DEVESH	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,793	HAGEMAN ET AL.	
	Examiner	Art Unit	
	Devesh Khare	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,19,21-25 and 28-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,19,21-25 and 28-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The finality of the Office Action mailed on 10/20/2003 has been withdrawn.

The resubmission of amendment after final filed on 03/30/2004 is acknowledged. Claims 1-17,20 and 26-27 have been cancelled. Claims 29, 31 and 33 have been amended. Claims 18-19, 21-25, and 28-34 are currently pending in this application. In view of the applicant's remarks the rejection of claims 18-19, 21-25, and 28-34 under 35 U.S.C. 103(a) as being unpatentable over Serfontein (U.S. Patent 5,631,271) in view of Paul et al. (U.S. Patent 5,292,538), has been withdrawn. The rejection of claims 18-19, 21-25, and 28-34 under 35 U.S.C., 112, first paragraph, has been overcome through applicants' amendment to the claims 29, 31 and 33.

During the course of reconsideration of the application, a prior art reference not previously disclosed by the applicants or the examiner came to light (see rejection below).

35 U.S.C. 112, second paragraph rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

Claims 18-19, 21-25, and 28-34 are rejected under the second paragraph of 35 U.S.C. 112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention of record.

(A) In claims 29, 31 and 33, line 3, the term "disorders" is vague and indefinite. The term "disorders" is not particularly defined, and the definition is indeed critical to the method of treatment. It is unclear what disorders are treated in the serotonin- or melatonin-

mediated illness. The term "disorders" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

(B) The term "a suitable for the treatment" in claim 29, is a relative term, which renders the claim indefinite. The term "a suitable for the treatment" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

(C) Claims 29 and 31 are vague and indefinite. Claims 29 and 31 fail to particularly point out the identity or name of the "carbohydrates, fats and proteins".

Claims which depend from an indefinite claim which fail to obviate the indefiniteness of the claim from which they depend are also seen to be indefinite and are also rejected for the reasons of record.

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 29 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,613,367 ('367) in view of DeWille et al. (U.S. Patent 6,475,539)('539).

The instant invention is directed to a pharmaceutical composition comprising carbohydrates, fats and proteins, and containing more than 44 ug up to 4000 ug of folic acid, more than 0.8 ug up to 2000 ug of vitamin B12 and more than 50 ug up to 10,000 ug of vitamin B6 per 100 kcal of said carbohydrates, fats and proteins, and further containing at least one of riboflavin, thiamine, niacin and zinc.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the '367 patent discloses a nutrition composition comprising proteins, peptides and amino acids (claim 1); further comprising carbohydrates (claim 7); folic acid more than 30 ug, vitamin B6 more than 50 ug and vitamin B12 more than 0.1 ug (claim 6); and riboflavin, thiamine, niacin and zinc are also disclosed in Table 2 (cols. 8-9). It is noted that the said compositions are characterized by providing per 100 kcal. The '367 patent differs from the applicant's invention that the composition of the '367 patent does not claim the use of fats.

The '539 patent teaches the use of fats (edible oil) in an enteral formula (claim 1). The '539 patent discloses that fats provide sufficient number of calories in a nutrition product (col. 16, lines 46- 59).

It would have been obvious to a person having ordinary skill in this art at the time the invention was made, to modify the nutrition composition containing proteins,

carbohydrates, folic acid, vitamin B6, vitamin B12, riboflavin, thiamine, niacin and zinc as taught by the '367 patent by adding the fats that provide sufficient number of calories as evidenced by the '539 patent. The motivation to obtain the instantly claimed compositions is provided by the '367 patent, since the prior art suggests that the said nutrition product has a beneficial effect for improving feelings of well being, compensation of immaturity and problems in the metabolic capacity of the infant (col.1, lines 5-8).

The examiner notes the instant claims and the '367 claims do indeed substantially overlap and this obviousness-type double patenting rejection is necessary to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees.

2. A review of the prior art revealed no references that could be appropriately applied on the claims 18-19, 21-25, 28, 30-34 directed to method for the treating serotonin- or melatonin-mediated disorders with folic acid, vitamin B6 and B12 and at least one component selected from the groups consisting of riboflavin, thiamine, niacin and zinc, wherein folic acid is more than 44 µg, vitamin B12 more than 0.8 µg, vitamin B6 more than 50 µg and atleast 0.55 mg of niacin and/or at least 0.08 mg of riboflavin and/or at least 55 µg of thiamine, with further comprising carbohydrates, fats and proteins.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Devesh Khare whose telephone number is 571-272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 571-272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,J.D.
Art Unit 1623
June 29,2004

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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